17. (New) A drug delivery composition according to claim 1, wherein the drug is budesonide.

REMARKS

Claims 1-17 are pending in the application. New claims 14-17 have been added. No new matter is added by the addition of the new claims, as support for the subject matter of the new claims is found in the specification at least at page 8, lines 14-23.

For the Examiner's convenience, a complete set of all pending claims is attached to this response.

I. Examiner's Office Action (Paper No. 8).

As a threshold matter, the applicant submits that Paper No. 8, as modified by the Petition Decision dated June 17, 2002 ("Petition Decision"), is an improper Office Action. Accordingly, the applicant requests that the next Office Action, if any, is not made final, so the applicant may have at least one full and fair opportunity to address the Examiner's rejections and the bases therefor, before a final Office Action is issued.

Paper No. 8, even as modified by the Petition Decision, is an improper Office Action on several grounds. First, as pointed out in the Request for New Non-Final Office Action filed by the applicant on April 26, 2002, Paper No. 8 is not responsive to the applicant's communications and arguments presented in the Amendment filed October 16, 2001. Specifically, in Paper No. 8, the Examiner has failed to fully address the applicant's arguments relating to the § 103 rejection over Kelm. The M.P.E.P. specifies that a final rejection should include a rebuttal of any arguments raised in the applicant's reply, M.P.E.P. § 706.07; therefore as an incomplete rebuttal is provided in Paper No. 8, the Office Action is improper, and consequently the applicant has not had an opportunity to address the Examiner's points.

Additionally, the text of Paper No. 8 as amended by the Petition Decision, is ambiguous as to the status of at least two of the rejections, and further, the text fails to provide an analysis upon which at least one of the rejections is based. It is unclear whether the § 102 and § 103 rejections, each based upon Kelm taken individually, are withdrawn, or are maintained. The Examiner sets out the rejections for each, and applies Kelm at pages 3-4. However, under the section entitled "Response to Arguments", the Examiner states that the § 102 rejection is withdrawn, issues a new § 103 combination rejection (Kelm-Mandel), but never clarifies the status of the § 103 rejection over Kelm taken individually.

Additionally, the new rejection presented in Paper No. 8 is defective both formally and substantively, and cannot be appropriately addressed by the applicant. The Petition

Decision clarifies that the § 103 rejection based upon the Kelm-Mandel combination is a new rejection, involving the citation of a new reference (Mandel). However, in Paper No. 8, the Examiner has failed to meet the minimum formal and substantive requirements associated with such rejection. A "Notice of References Cited" listing Mandel was not provided, nor was the applicant supplied a copy of Mandel. More significantly, the Examiner has failed to provide the applicant with a meaningful explanation of how she proposes to make such combination and how she believes each element of the *prima facie* case of obviousness to be met. Consequently, because none of these actions was undertaken, the Office Action is improper.

Finally, the Petition Decision which substantively modified the contents of Paper No. 8, thereby materially affecting the applicant's strategy for response, was not received by the applicant's representative until nine business days before the six month deadline for response to the Office Action. The Petition Division erred in mailing the Petition Decision to applicant's previous attorney, not the attorney who submitted and signed the Request for a new Non-Final Office Action, and who is the applicant's Rule 34(b) representative.

In view of the foregoing, it is submitted that the applicant has been denied a full opportunity to analyze, consider, and craft a response to the Office Action, as modified, because of compounded errors on the part of the U.S. Patent and Trademark Office.

Thus, it is respectfully requested that, if the Examiner should decide to issue a subsequent Office Action, that Office Action is designated non-final, to afford the applicant at least one full and fair opportunity to formulate a reasonable, substantive rebuttal to each of the Examiner's arguments, before a final Office Action is issued. Additionally, it is requested that this non-final Office Action contain: (i) a Notice of References Cited, listing Mandel; (ii) a clear statement that the § § 102 and 103 rejections over Kelm individually, are withdrawn or maintained, and if maintained, a clear reasoned analysis that meets the requirements of M.P.E.P. 706, explaining why the applicant's argument are not persuasive; and (iii) a full, reasoned basis for the rejection of the claims under 35 U.S.C. § 103 based upon the Kelm-Mandel combination.

II. Double Patenting Rejection.

At pages 2-3, the Examiner has maintained the rejection of claims 1, 2, 5, 6, and 8-13 under the judicially-created doctrine of obviousness-type double patenting over claims 1-8 of U.S. Patent No. 6,228,396 B1. As indicated in the response filed by the applicant's representative on October 11, 2001, the applicant will file a Terminal Disclaimer to overcome this rejection when all other rejections have been withdrawn and the Examiner has indicated that the claims are allowable as to all prior art of record.

III. Rejection Under 35 U.S.C. § 102 Based Upon Kelm.

At page 4 of Paper No. 8, the Examiner states that "the rejection under 35 U.S.C. § 102(e) as being anticipated by Kelm, *et al.*, U.S. Patent No. 5,686,105, has been withdrawn." Accordingly, the applicant assumes that this rejection has been withdrawn in view of their prior response and will not address it herein. In the event that the Examiner did not intend to withdraw this rejection, the applicant traverses this rejection for at least the reasons set out in their response, dated October 11, 2001, the contents of which are incorporated herein by reference, and request that the Examiner's position is made clear in any subsequent Office Action.

IV. Rejection Under 35 U.S.C. § 103 Based Upon Kelm.

At page 4, the Examiner has rejected claims 1-13 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,686,105 to Kelm, *et al.* As reasoning for this rejection, the Examiner states that "it would have been obvious to one of ordinary skill in the art to, by routine experimentation, modify Kelm's composition . . . to obtain a desirable pharmaceutical oral dosage form that his suitable for colonic delivery to treat colonic diseases." It is unclear from the text of Paper No. 8 whether this rejection has been withdrawn, as the Examiner made no comment, except to impose a new rejection (discussed below). If it has not been withdrawn, the applicant traverses the rejection for at least the reasons set forth below.

The composition disclosed in Kelm does not render the claimed invention obvious as it fails to teach or suggest each element of the invention. Specifically, Kelm does not teach or suggest use of a starch capsule. As the applicant has pointed out in a prior Office Action response, the starch capsule of Kelm is afforded the prior art date of May 17, 1995. Neither of U.S. Patent Nos. 5,631,022 (filed July 6, 1995) and 5,514,663 (filed October 19, 1993), related patents to which the Kelm patent claims priority, discloses use of a starch capsule. The present application has an effective date of June 21, 1994. Therefore, the starch capsule of Kelm is not prior art to this application.

Further, the Examiner has pointed to no motivation in Kelm which would have caused a person of ordinary skill to modify the prior art disclosures of Kelm to arrive at the present invention as claimed. There is no teaching in those portions of Kelm having a § 102(e) date antecedent to the effective date of this application that would have caused a person of ordinary skill to modify the gelatin capsule of Kelm and arrive at the present invention as claimed.

Accordingly, for at least the reason given above, the rejection under 35 U.S.C. § 103(a) over Kelm should be withdrawn, if it has not already been.

V. Rejection Under 35 U.S.C. § 103 Based Upon Kelm-Mandel

In the "Response to Arguments" section of Paper No. 8, as modified by the Petition Decision, the Examiner has issued a new rejection based upon the combination of Kelm-Mandel. As noted above, this rejection is not a proper rejection; the Examiner has failed to cite Mandel in the application under Notice of References Cited, failed to provide a copy of such reference to the applicant, and, most significantly, the Examiner has failed to apply the combination to the claims, and therefore has not properly articulated a showing of the requisite *prima facie* case of obviousness. However, insofar as the applicant can discern the Examiner's basis for rejection, the applicant traverses the rejection.

First, the Kelm-Mandel combination does not teach or suggest each element of the claimed invention. For reasons discussed above, the starch capsule subject matter disclosed in column 8 of Kelm is not prior art to the present application, as at least the starch capsule of Kelm has a § 102(e) date of May 17, 1995. The addition of the disclosures of Mandel does not remedy this deficiency, for Mandel does not teach or suggest use of a starch capsule for the picosulfate composition disclosed therein.

The Examiner seems to suggest that a person of ordinary skill would have been motivated to modify the compositions of Mandel and/or Kelm by substituting the disclosed gelatin capsules with a starch capsule. To the contrary, a person of ordinary skill would not have been motivated to make this modification, since neither Kelm nor Mandel provides any motivation or suggestion to modify the gelatin capsule to use a starch capsule. The Examiner asserts that a person of ordinary skill would have modified the gelatin capsule to arrive at the starch capsule in order to develop a "capsule that is suitable for colonic delivery." However, both of the compositions of Kelm and Mandel, which use gelatin capsules, are already taught as being useful for colonic delivery. Thus, a person of ordinary skill would not have been motivated to make the modification as suggested by the Examiner.

Accordingly, for at least the reasons given above, it is respectfully requested that the Examiner reconsider and withdraw the rejection under 35 U.S.C. § 103(a) over the Kelm-Mandel combination. However, if the Examiner maintains such rejection, it is respectfully requested that the Examiner issue a Notice of References Cited listing Mandel, provide a copy of Mandel, and suggest a reasoned basis for the rejection over the Kelm-Mandel combination, so the applicant may fully address the Examiner's bases for rejection.

CONCLUSION

For at least the reasons given above, it is respectfully requested that all claims are in condition for allowance. Accordingly, it is requested that the Examiner reconsider and allow the claims at the earliest opportunity. In the event that the Examiner issues a new Office Action, it is requested that the new Office Action is non-final.

Respectfully submitted,

PETER WATTS

3 July 2002
(Date)

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WWS/KAB:vj

Enclosures: *Petition for Three-Month Extension of Time*
Complete Set of Pending Claims